UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

EPA United States Environmental Protection Agency Office of Pesticide Programs

MEMORANDUM

11/27/2018

SUBJECT: Acute Toxicity Review for Panther, EPA Reg. No.: 5813-RRT

FROM: Lindsay O'Dell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Jenny Tao, Senior Scientist (Acute Toxicology) 11/27/2018
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

TO: Demson Fuller, PM Team 32 / Benjamin Chambliss
Regulatory Management Branch I
Antimicrobials Division (7510P)

Registrant: The Clorox Company		
Decision No.: 542410	Submission No.: 1021787	E-Sub No.: 30427
DP No.: 448237	Action Code: A540	
MRID No(s).: -		

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
014703	7681-52-9	Sodium hypochlorite	3.0%
		Other Ingredients	97.0%
		Total	100%

I. BACKGROUND

The Registrant, The Clorox Company, has submitted an application for pesticide registration for their product: *Panther*, EPA Reg. No. 5813-RRT, which contains 3.0% Sodium hypochlorite as the active ingredient. The Registrant has selectively cited acute toxicity data on four registered products, *Puma*, EPA Reg. No. 5813-100, *Clorox Bleach*, EPA Reg. No. 5813-1, *Fresh Scent Clorox*, EPA Reg. No. 5813-20, and *Ultra Clorox Brand 6.15% Bleach*, EPA Reg. No. 5813-52. Additionally, a waiver request was submitted to fulfill the acute dermal toxicity data requirement. The proposed product is formulated for use as a laundry sanitizer and household disinfectant.

II. FINDINGS/RECOMMENDATIONS

In order to address the acute toxicity data requirement, the registrant has selectively cited the following products that are provided in Table A below.

Table A. Summary of selectively cited products.

Cited Product	A.I. concentration	Data Requirement	Accepted Toxicity Category	MRID
5813-100	8.25%	Acute Oral Acute Dermal Acute Inhalation	IV IV IV	48216901 48216902 48017502
5813-1	5.25%	Eye Irritation	II	44758201
5813-20	5.25%	Skin Irritation	IV	00125731/43950801
5813-52	6.15%	Skin Sensitization	Non-sensitizer	46672302

1. Acute Oral Toxicity

The Agency previously reviewed MRID 48216901 to support the registration of *Puma,* EPA Reg. No. 5813-100 (DP382375; 2010), and the estimated LD_{50} is >5000mg/kg. The Agency finds EPA Reg. No. 5813-100 to be toxicologically relevant to the proposed product thus the data may be bridged to support this endpoint.

2. Acute Dermal Toxicity

The Registrant has cited the Agency's *Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis (11/9/16)* to waive the acute dermal study for the proposed product. However, an acute oral toxicity study was not conducted on the proposed formulation; therefore, the request to waive the acute dermal endpoint is not granted. The Agency recommends fulfilling the acute dermal toxicity data requirement with the same approach as the acute oral toxicity. The data submitted for EPA Reg. No. 5813-100, MRID 48216902, may be bridged to support this endpoint.

3. Acute Inhalation Toxicity

The Agency previously reviewed MRID 48017502 to support the registration of *Puma*, EPA Reg. No. 5813-100, in 2010, and the estimated LC_{50} is >2mg/kg. The Agency finds EPA Reg. No. 5813-100 to be toxicologically relevant to the proposed product thus the data may be bridged to support this endpoint.

4. Primary Eye Irritation

The Registrant has cited MRID 44758201 which was submitted to support the reregistration of EPA Reg. No. 5813-1. Signs of irritation in the unwashed eyes of 6 of 6 rabbits cleared by day 14, placing the cited product in toxicity category II. However, the formulation of the proposed product contains additional corrosive inert ingredients, as well as, a higher pH (see confidential attachment). Due to these formulation differences the data cited may not be adequate to characterize potential eye irritation property of the proposed product Considering the corrosive pH (13) of the proposed product, the Agency recommends waiving the primary eye irritation study and assigns toxicity category I.

5. Primary Skin Irritation

The Registrant has cited MRID 00150262/00125731/43950801 which was submitted to support the reregistration of EPA Reg. No. 5813-1 and 5813-20. The study report showed only 3/6 rabbits showed slight erythema at 72 hours, placing the cited product in toxicity category IV. However, the formulation of the proposed product contains additional corrosive inert ingredients, as well as, a higher pH (see confidential attachment). Due to these formulation differences the data cited may not be adequate to characterize potential skin irritation property of the proposed product. Considering the corrosive pH (13) of the proposed product, the Agency recommends waiving the primary skin irritation study and assigns toxicity category I.

6. Dermal Sensitization

The Registrant has cited MRID 46672302 conducted on *Ultra Clorox Brand 6.15% Bleach*, EPA Reg. No. 5813-52, to fulfill this data requirement. The Agency finds the cited study to be toxicologically relevant to the proposed product and the cited data may be bridged.

7. The acute toxicity profile of *Panther*, EPA Reg. No. 5813-RRT is currently:

Study	MRID	Toxicity Category	Status
Acute Oral Toxicity	48216901	IV	Bridged
Acute Dermal Toxicity	48216902	IV	Bridged
Acute Inhalation Toxicity	48017502	IV	Bridged
Primary Eye Irritation	-	I	Waived
Primary Skin Irritation	-	I	Waived
Dermal Sensitization	46672302	Nonsensitizer	Bridged

III. CONCLUSION

The acute toxicity data requirements have been met to support the registration of the proposed product EPA File Symbol 5813-RRT, *Panther*.

IV. PRODUCT LABELING

1. Signal Word: **DANGER**

2. The statement, "Keep Out of Reach of Children (KOROC)" is required. It should appear immediately above the front panel signal word "DANGER".

3. The Agency's *Label Review Manual* (https://www.epa.gov/sites/production/files/2017-09/documents/lrm-complete-aug-2017.pdf) indicates the following human-hazard precautionary statements:

HAZARDS TO HUMANS and DOMESTIC ANIMALS:

DANGER: Corrosive. Causes irreversible eye damage and skin burns. Do not get in eyes, on skin, or on clothing. Wear protective eyewear. Wear long-sleeved shirt and long pants, socks, and shoes and chemical resistant gloves. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before use.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

FIRST AID:

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a Poison Control Center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. For general information on product use, etc., call the National Pesticides Information Center at 1-800-858-7378. You may also contact the poison control center at 1-800-222-1222 for emergency medical treatment information.

4. Restricted Use Classification

This product meets the Agency requirements for Restricted-Use Classification based on data that place it in toxicity category I for primary eye irritation. In lieu of assigning the product Restricted-Use classification, the product manager may consider

alternatives such as face shield or goggles (to mitigate the identified hazards). Restricted-Use requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR §152.170 for information on Restricted-Use products.

Based upon data placing it in toxicity category I for primary eye irritation, this product meets the Agency requirements for Child-Resistant Packaging (CRP). However, the Agency does not require products that are assigned Restricted-Use status to be placed in CRP in addition to Restricted-Use Classification. CRP requirements vary depending upon use sites, e.g., institutional use, residential use, etc. Please refer to the 40 CFR, §157.22 and 157.24 for CRP requirements and exemptions. Thus, CTT recommends that the Product Manager assign this product Restricted-Use classification; if not, the registrant should place this product in CRP.

Inert ingredient information may be entitled to confidential treatment